UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 12/9/2020

Subject: Efficacy Review for Raptor 5, EPA Reg. No. 4091-22
(DP Barcode: 459549) (E-Sub: 53276)

From: Samantha Collins
Efficacy Branch
Antimicrobials Division (7510P)

Thru: Thao Pham, Team Lead
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: December 9, 2020

To: Jacqueline Hardy / Lorena Rivas
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: W.M. Barr & Company Inc
6750 Lenox Center Court, Suite 200
Memphis, TN 38115

Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl* dimethyl benzyl ammonium chloride (*50%C14, 40%C12, 10%C16)	0.32%
Octyl decyl dimethyl ammonium chloride	0.24%
Didecyl dimethyl ammonium chloride	0.12%
Dioctyl dimethyl ammonium chloride	0.12%
Citric acid	2.50%
Other ingredients	96.70%
Total:	100.00%

I BACKGROUND

Product Description (as packaged, as applied): RTU Spray

Submission type: Amendment

Currently registered efficacy claim(s): RTU spray disinfectant (bactericidal, virucidal), non-food contact sanitizer, residual sanitizer (24 hours) and fungistat

Requested action(s): Addition of virucidal organisms and marketing claims

Documents considered in this review:

- Letter from applicant to EPA dated July 31, 2020
- Data Matrix (EPA Form 8570-35) dated July 31, 2020
- 3 new efficacy studies (MRIDs 51079201, 51079202, 51079203)
- Proposed label 7/31/2020
- Confidential Statement of Formula (EPA Form 8670-4), dated 1/14/2020.

II PROPOSED DIRECTIONS FOR USE

"[{Disinfecting] [Directions]
Hold container 6"-8" from surface and spray until thoroughly wet.
TO DISINFECT [Bacteria][and viruses† on]Hard, non-porous surfaces: Let stand for 5 minutes. Then wipe with a [damp] cloth [or sponge][or paper towel]. Preclean heavily soiled surfaces.
[Kills [effective against] [99.9% of] {Insert disinfection bacteria and viruses from Table A.}"

III STUDY SUMMARIES

1.	**MRID**	51079201	**Study Completion Date:**		2/23/2018		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus Lab Services, A24632					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Human Immunodeficiency Virus type 1, Strain HTLV-lllB					
Indicator Cell Culture		MT-2 cells					
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Application Method		RTU trigger spray					
Test Substance Preparation	**Name/ID**	Raptor 5					
	Lots **☐ 1 ☒ 2 ☐ 3**	KK006-082 and KK006-083					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		**Contact time**	4.5 minutes	**Temp**	22°C	**RH**	N/A
Neutralizer		Sephadex Gel Filtration					
Reviewer comments (i.e. protocol deviations etc.)		The initial assay, performed on January 2, 2018, was terminated prior to the completion of incubation due to cytotoxicity that may have resulted in invalid test results due to the inability to demonstrate at least a 3 log reduction in titer beyond the cytotoxic level. Testing was repeated on January 25, 2018, resulting in valid data which is presented in the body of this report.					

2.	**MRID**	51079202	**Study Completion Date:**				2/22/2018
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus Lab Services, A24654					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus					
Indicator Cell Culture		bovine turbinate (BT) cells					
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Application Method		RTU trigger spray					
Test Substance Preparation	**Name/ID**	Raptor 5					
	Lots **☐ 1 ☒ 2 ☐ 3**	KK006-082 and KK006-083					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% horse serum					
Carrier type, # per lot		Glass petri dish, 2 per batch					
Test conditions		**Contact time**	4.5 minutes	**Temp**	20°C	**RH**	N/A
Neutralizer		Sephadex Gel Filtration					
Reviewer comments (i.e. protocol deviations etc.)		The initial assay performed on January 4, 2018 was repeated on January 25, 2018 due to test substance cytotoxicity preventing demonstration of a 3-log reduction in titer beyond the cytotoxic level. Valid results were obtained from the assay performed on January 25, 2018.					

3.	**MRID**	51079203	**Study Completion Date:**				2/22/2018
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus Lab Services, A24634					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus					
Indicator Cell Culture		hepatocytes					
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Application Method		RTU trigger spray					
Test Substance Preparation	**Name/ID**	Raptor 5					
	Lots **☐ 1 ☒ 2 ☐ 3**	KK006-082 and KK006-083					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		100% duck serum					
Carrier type, # per lot		Glass petri dish, 2 per batch					
Test conditions		**Contact time**	4.5 minutes	**Temp**	21.5°C	**RH**	N/A
Neutralizer		Sephadex Gel Filtration					
Reviewer comments (i.e. protocol deviations etc.)		N/A					

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			KK006-082	KK006-083	
4.5-minutes, RTU trigger spray, 5% FBS					
51079201	Human Immunodeficiency Virus type 1, Strain HTLV-lllB	10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation	5.50
		Log_{10} $TCID_{50}$/carrier	≤2.50	≤2.50	
		Log Reduction	≥3.00	≥3.00	

MRID	Organism	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)	
			KK006-082		KK006-083			
4.5 minutes, RTU trigger spray, 5% horse serum								
			Rep #1	Rep #2	Rep #1	Rep #2	Rep #1	Rep #2
51079202	Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus	10^{-2} to 10^{-4} dilution	Complete inactivation		Complete inactivation		5.00	4.75
		Log_{10} $TCID_{50}$/100µl	≤1.50		≤1.50			
		MPN Log Reduction	≥3.30					
4.5 minutes, RTU trigger spray, 100% whole duck serum								
51079203	Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus	10^{-2} to 10^{-4} dilution	Complete inactivation		Complete inactivation		5.25	5.25
		Log_{10} $TCID_{50}$/250µl	≤1.50		≤1.50			
		MPN Log Reduction	≥3.68					

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51079201	Disinfection, virucidal	Hard non-porous surface	Spray RTU	4.5-minutes	5% FBS	N/A	Human Immunodeficiency Virus type 1, Strain HTLV-lllB	**Yes**
51079202	Disinfection, virucidal	Hard non-porous surface	Spray RTU	4.5-minutes	5% horse serum	N/A	Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus	**Yes**
51079203	Disinfection, virucidal	Hard non-porous surface	Spray RTU	4.5-minutes	100% duck serum	N/A	Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus	**Yes**

VI LABEL COMMENTS

4091-22/ dated 7/31/20

1. The proposed label claims that the product, Raptor 5, a RTU liquid spray is an effective virucidal disinfectant against the following on hard non-porous surfaces with a 5% soil load at a 5-minute contact time:

   Human Immunodeficiency Virus type 1, Strain HTLV-lllB
   Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus
   Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus

   These claims are **acceptable** as they are supported by the submitted data.

2. Make the following changes to the proposed label:

   a. Throughout the label,
      i. revise “heavily soiled” to “visibly soiled”. Recommend that directions for “let stand” be revised to “allow surface to remain visibly wet for [insert contact time]”.
      ii. Revise terms such as “fight”, “fights”, “fighting” bacteria as these terms are misleading regarding the activity of the product. These terms may be revised to “kill” or “effective against” as they are more literal terms.
      iii. When cleaning and disinfection terms are used to describe “one-step” in the same claim, the claim should be qualified to add “when used according to the directions for use for disinfection.” The same applies to sanitization and cleaning terms describing “one-step” (i.e., “when used according to the directions for use for sanitization”).
      iv. Recommend the registrant to consider adding a section where all the qualifiers are summarized to facilitate readability of the label.

   b. On page 6 of the label, remove “powered by Microban” or revise to specify cleaning only as the existing claim implies enhanced efficacy

   c. On pages 9 and 10, remove “antimicrobial” as a description for sanitization. Sanitization claims were only substantiated by bacterial efficacy data.

   d. On page 9, 10 and 11 under “Sanitizing Claims” and “24 Hour Residual Sanitizing Claims”,
      i. Qualify each instance of “surfaces” to add “hard, nonporous” as a descriptor to accurately reflect the intended type of surfaces for treatment.
      ii. Revise “All-Purpose” to “multi-purpose” in the claim “[Antibacterial][Antimicrobial] All-Purpose Cleaner.” Remove “antimicrobial”.
      iii. Remove brackets from “for up to 24 hours” in the claim “[Patented][Patent Pending] formula [continues to work after multiple touches] [for up to 24 hours].”
      iv. For 24 hour residual claims, specify “on hard nonporous surfaces”
      v. Remove “…7 day mold and mildew protection]” from the claim “[Provides 24 hour residual antibacterial control] [and] 7 day mold and mildew protection].” Mold and mildew claims should not be listed under sanitization heading.

vi. Remove the following claims: “bacteria fighting power”, and “[This product] [is] the ultimate 24 hour bacteria defender” as these claims imply a heightened efficacy of the product.

e. On page 12 of the proposed label,
   i. claims such as “Long-lasting protection *against bacteria”, “Around-the-clock protection *against bacteria”, and “Day and night protection against bacteria” must be qualified with a 24-hour time frame.
   ii. Remove the brackets from “99.9%” so that it is not optional language specifically when used in conjunction with the term “eliminates” as the claims may imply complete kill. Ensure each instance of “eliminates” is followed by “99.9%” in reference to public health claims.
   iii. remove the claim “Protection of the things that matter most”, as this claim may be misleading to the user.

f. On page 13,
   i. Under the sections “Fabric Mildewstat Claims” and “Hard Surface Mildewstat Claims”, qualify “fungi”, “fungus”, and “fungal spores” to add “which cause mildew stains on fabric articles” or with “nonpathogenic fungi/fungus/fungal spores” to be consistent with the testing method and guidance for this use.
   ii. Revise “Meets OSHA standard for bloodborne pathogens surface disinfection” to “Meets surface disinfection recommendations under OSHA’s Bloodborne Pathogens Standard”

g. On page 14 of the label, emerging viral pathogen claims should be updated to follow current format for consistency. Supporting viruses from an approved Terms of Registration should be referenced in the table below:

   “This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

   This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

   -Enveloped Viruses
   - Large non-enveloped viruses

For an emerging viral pathogen that is an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	
Large non-enveloped viruses	

   Acceptable claim language:

   [Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard, non-porous surfaces. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]***

*on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.*

***[Name of illness/outbreak]** is caused by **[name of emerging virus]. [Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.*"

h. On page 16, specify that "stovetops" should be at room temperature for treatment.

i. On page 22, specify "exterior" for toilet graphic.

Note to PM:
On page 14 lists surface materials (Table 1) that include Copper, Nickel, Zinc, and Tin as these are chemical elements that could react with the product. Please verify for acceptability.